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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,436	06/30/2003	Istvan Toth	36677.11	9341

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,436	TOTH ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-28* is/are pending in the application.

4a) Of the above claim(s) *18 and 21-23* is/are withdrawn from consideration.

5)☒ Claim(s) *16-17 and 24* is/are allowed.

6)☒ Claim(s) *1,3-13,157,19 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 11/14/2005 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2 and 14 have been canceled.

2. New Claims 24-28 have been added.

3. Claims 1, 4, 6, 8 and 11-12 have been amended.

4. Remarks drawn to claim objections and rejections under 35 USC 112, second paragraph and 102,

Claims 1, 3-13 and 15-28 are pending in the case. Claims 18 and 20-23 have been indicated as withdrawn.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 8 has been overcome by amendment.

Claim 12 is objected to because of the following informalities: In claim 12, the terms "be hydrogen" have been recited twice.

Claims 3 and 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 15, which are drawn to a compound of claim 1 recite that D (in the compound of claim 1) is a biological molecule. Claim 1 recites that

D is selected from Markush members drug, peptides, protein, nucleic acid, mono- and oligosaccharides and sugar-peptide conjugates, which are all seen as biological molecules. The recitation of "biological molecule" in claims 3 and 15 is not seen to further limit the parent claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 1-17 and 19 under 35 USC 112, second paragraph have been overcome by amendments to claims 1, 4, 6, 11, 12 and cancellation of claims 2 and 14.

The following rejection under 35 USC 112, first paragraph is made of record necessitated by amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-13, 15-17,19, 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a complex of formula I in instant claim 1 for D being piperacillin (a beta-lactam antibiotic containing the piperazine core) does not reasonably provide enablement for complexes with any drug or biological molecule as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The level of one of ordinary skill
(C) The amount of direction provided by the inventor
(D) The existence of working examples
(E) The level of predictability in the art
(F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The recitation in claim 1, namely a complex of general formula I, wherein D is a drug and in claims 4 and 15, wherein D is a biological molecule, is a broad recitation. The term drug and biological molecule are also seen to reasonably include not only any known compound but also unknown compounds as of the filing date.

The level of one of ordinary skill in the art

The level of skill of those in this art is that of one having experience in organic synthesis and developing pharmaceuticals.

The amount of direction provided by the inventor

The specification (page 7) defines D as a therapeutically useful molecule such as a drug. This is a very broad definition. The CAFC further clearly states "A written description of an invention requires a precise definition, such as by structural formula or chemical name, of the claimed subject matter sufficient to distinguish it from other materials. One skilled in the art therefore cannot visualize or recognize the identity of the members of the genus.

The existence of working examples

The working example (Example 7, page 41) set forth in the instant specification is drawn to a complex according to the general formula I wherein D is the drug Peperacillin. One of ordinary skill in the art will not extrapolate this to complexes comprising any drug since the example provided is not representative of all drugs and ionic complexes encompassed by the recitation of instant claim 1.

The level of Predictability in the Art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427.2d 833, 166 USPQ (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since on of skill in the art cannot fully visualize or recognize the identity of the members of the genus. In the absence of fully recognizing the identity of the members of the genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any of the complexes comprising the drugs herein. Goodman and Gilman's "The Pharmacological Basis of Therapeutics", 10th Ed., 2001, page 54, teaches that the frequency of significant beneficial or adverse drug interactions is unknown (bottom of the left column at page 54). Relatively small changes in the drug can have significant adverse consequences. In the instant case one of skill in the art would not be able to fully predict possible adverse drug-drug interactions and incompatibilities occurring with the many combinations of any complexes having the drugs claimed herein. Thus, the teachings of Gillman and Goodman clearly support that the instantly claimed invention is highly unpredictable.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent all the complexes encompassed by the recitation of the instant claims. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention. Since any structural variation to a compound would be reasonably expected to alter is properties, one of ordinary skill in the art would be required to perform undue experimentation to determine which, if any, other compounds of the term "drug" would be useful and compatible to make a complex of instant formula 1as recited in instant claim 1.

Conclusion

1. Claims 1, 3-13, 15,19, 25-28 are rejected,

2. Claims 16-17 and 24, drawn to a complex of formula 1, wherein D is a sulfated oligosaccharide, charged oligosaccharide, sulfated antithrombotic or an aminoglycoside, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

4/5/06

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623